

ENES5 AGENDA

Session Topic Descriptions

Pre-reading document



2. PROGRESS ON THE CSR/ES ROADMAP

Objectives:

The CSR/ES Roadmap is a cross-stakeholder initiative and it sets out a rolling plan of actions to 2018 towards good quality information in the safe use of chemicals in the REACH chemical safety report and the extended safety data sheet. The 21 actions combined cover the logical sequence of steps in gathering, assessing and communicating information on chemical substances.

Objectives at ENES5 are

1. Review the progress since ENES4 (e.g. publication, web site, first implementation plan (Q3-Q4/2013).
2. Discuss, and make proposals for, the priorities for the second implementation plan (Q1-Q2/2014).
3. Survey on ways to improve the Roadmap web site as a communication tool e.g. disseminating information, attracting new sectors & stakeholders to the action areas.

Expectations from ENES5:

Understanding and input on the way forward in 2014 in implementing the CSR/ES Roadmap actions.

Input for improving the dissemination of actions concluded.

More detailed description of the Task Force:

Not a Task Force as such. On governance, the Roadmap document called for a **Roadmap Coordination Group** that will monitor the implementation of the roadmap and will review the roadmap every second year (i.e. first review due mid-2015). The ECHA-stakeholder *Exchange Network on Exposure Scenarios* (ENES) will act as a platform for sharing the information on concluded actions and agreeing on best practices.

Of the Member State authorities, Austria, Germany, Italy, the Netherlands, Poland and the United Kingdom have confirmed their continued participation in the Roadmap Coordination Group alongside the industry sector organisations of Cefic, Concawe and DUCC and Eurometaux. In addition, Finland has expressed its interest to join.

Results after ENES4

1. Publication of CSR/ES Roadmap on 17 July 2013.
2. Creation of Roadmap web site.

1.2 MATTERS ARISING, new topics on the horizon

TITLE:

- Storage of Exposure Scenarios
- DU ES Conformity concept and Tool

Objectives:

To identify topics of potential interest which are not yet discussed in ENES but which are relevant for an improved implementation of ES.

Expectations from ENES5:

Two topics of potential interest will be presented in a few slides. The presentation should address how these topics fit into the roadmap. Based on the outcome of the discussions it should be decided whether the presented topics should be further investigated and whether resources can be allocated. The expectation is that ENES decides whether the topic is relevant for ENES and will be handled in the next ENES meeting. (Criterion for relevance is that a topic attracts sufficient people to work on a topic.)

More detailed description of the Task Force:

One presentation covering the two identified topics: Storage of exposure scenarios and Environmental information in SDS for mixtures. The second introduces a concept of integrating scaling and a simplified DU CSA process (including generation of information for notification to ECHA) into one tool based on standardized input information made available by suppliers.

Results of the TF after ENES4

It is a new task force, therefore so far no result!



2.1 ES SHORT TITLES

(RM 4.2)

TITLE: - Rules for Building and Structuring ES Short Titles

ES SHORT TITLES Objectives:

Following discussions at ENES3 and ENES4 meetings, the ES Short Titles team organised a workshop to further assess and refine the proposed rules for building standardised and structured ES Short Titles.

The workshop conclusions, updated rules, more worked examples and next steps will be presented at ENES5.

Expectations from ENES5:

ENES5 participants are expected to share additional feedback they may have on updated rules or ask questions for clarification (a pre-reading document with updated rules will be used).

Support from the "IT-community" will be sought to test the rules in IT-systems as a next step.

More detailed description of the Task Force:

The remit of this team is to come up with a clear proposal for structuring and building ES titles for the main purpose of helping DUs navigate through extended SDS and easily recognise ES that apply to their uses. The ES titles should be standardised so that ES tables of contents from different suppliers and different substances appear similar.

ENES is seen as the umbrella for discussing the proposed rules and disseminating the findings.

Results of the TF after ENES4

Workshop to address open issues identified at ENES4, involving a number of IT-providers (September 2013)

- Updated rules for structured ES Titles
- List of outstanding questions and issues (rules and IT)
- Follow-up activities and draft implementation plan (post-ENES5)

2.2 ECom phrases and XML (RM 3.3)

- TITLE:**
- ECom Phrases, Building for the future
 - ECom XML: Latest updates on the project development

ESCOM XML (Library) Objectives:

Inform ENES5 about current state and next steps of ECom project.

Expectations from ENES5:

No input from ENES5 required (suggestions are welcome, will be considered, but ECom operates independently from ENES)

More detailed description of the Task Force:

New organisational setup with one CEFIC-led organisation that looks at ECom phrases and one IT-provider-led organisation that develops ECom XML.

Results of the TF after ENES4

Issue among intellectual property is resolved. Presentation in ENES4 follow-up session.



2.4 Specific Consumer Exposure Determinants (RM 2.5)

TITLE: - SCEDs the way ahead (Industry)
 - SCEDs in CHESAR (ECHA)

Presentation of the latest development on SCEDs, new functionality within CHESAR and ECETOC TRA as well as feedbacks from the workshop with MS/ECHA/industry

SCEDs Objectives:

The **SCEDs (Specific Consumer Exposure Determinants)** have been developed by **DUCC member associations**, which represent companies that use chemicals to formulate mixtures as finished products for end users, including consumers and professional users, and by **Concawe**, whose members sell formulated consumer products such as fuels and lubricants, as well as manufacture the petroleum substances used in such products. Participant DUCC members are A.I.S.E./FEA, CEPE and FEICA.

The **SCEDs** are a series of factsheets containing habits and practices (or other similar) data for a range of consumer products, which constitute refined exposure determinants to be used as “information input” in a consumer exposure assessment.

The SCEDs are primary meant to be used within ECETOC TRA. Specific Consumer Exposure Determinants (SCEDs) are meant as a tool to facilitate transparent and realistic exposure estimates for a broad range of consumer products.

The SCED factsheet template developed by industry enables sectors to document consumer exposure information in an harmonised way. It will present the information available in a transparent manner.

From the information contained in the factsheets, it will be possible to run an assessment with ECETOC TRA V3.1 in Chesar and thus to generate exposure scenarios and extended safety datasheet. The information available in the factsheets may also be beneficial for use in other assessment tools.

The final vision for the activity was to develop a comprehensive library of SCEDs that reflect the principle situations of use for consumer chemical products formulated by the involved sectors.

The SCEDs project is building on a previous project, the specific environmental release categories – spERCs.

Expectations from ENES5:

We would like to present to give an update on the project and hopefully pass the message that the SCEDs would become available in a close future- for real life testing in the CSR. We would also like to invite other trade groups to come forward with additional product category/ examples. Ahead of ENES meeting we are pleased to share the SCEDs template as well as an example generated by Chesar.

More detailed description of the Task Force:

- Harmonised SCED template and corresponding guidance on how to fill it in
- Illustrative SCED examples;
- SCED-related functionalities implemented in Chesar,
- (Foreseen) adaptation of the TRA consumer exposure estimation tool
- Conclusion on the acceptance of the approach – outcome of the technical workshop
- Way ahead of the SCEDs

Results of the TF after ENES4

As follow up of ENES4, DUCC and Concawe are currently refining the SCEDs template and the related guidance document. Work with ECHA is also ongoing in order to enable use of the SCEDs within the CHESAR tool. A workshop is organized on 13 November in order to exchange with Member States.



3.2 MIXTURES SAFE USE METHODOLOGY (RM 4.4)

TITLE: - Revised DU Guidance – Communication in the supply chain related to mixtures

- Overview methods currently being developed to determine and communicate safe use information for mixtures
- Introduction to the exercises for break-out sessions: How to do the comparison and what elements are important to address

SAFE USE METHODOLOGY Objectives:

Communicating relevant exposure scenarios information for substances in mixtures and other information for mixtures further downstream is a complex task for industry.

At previous ENES meetings it was clear that a lot of initiatives are going on to develop methodologies and approaches on how to deal with this challenge. However discussions at ENES 4 learned that there was a need to map, exemplify and compare the different methods in a systematic way.

Therefore Cefic and DUCC took the initiative to make an overview of ongoing initiatives. For each identified methodology / approach information with regard to applicability, relevant key processes, expected output, availability of supporting documents, etc. was mapped.

In addition methodologies/approaches already fully elaborated at this stage, were applied on “real life” examples to determine information on safe use of (substances in) mixtures in order to have more insight in the practical use, outcome and issues related to methodologies / approaches.

Expectations from ENES5:

During the plenary session the result of the mapping exercise will be presented. This presentation will give participants a general overview on what is currently available of methodologies/approaches in order to define and communicate information on safe use of (substances in) mixtures. This overview will also support in the identification of any remaining gaps and the areas for further work to meet the needs of the involved actors.

During the breakout sessions 4 methodologies will be discussed more in detail:

- 2 methodologies to identify substances that drives the selection of the relevant operational conditions and risk management measures mentioned in exposure scenarios of substances to be included in the safe use information for the mixture, namely:
 - The **critical component approach**(CCA) which identifies critical substances based on derived no effect levels (DNELs) and predicted no effect concentration (PNEC) for all substances and their concentrations in the mixture and
 - **CLP+** which identifies lead substances mainly based on the classification principles of the Classification, Labelling and Packaging regulation.
- 2 methodologies that identify safe use information for mixtures for typical uses, compositions and/or hazard profiles for products within specific sectors, namely:
 - The **GEIS** methodology which – based on typical contributing scenarios – identifies safe use information for detergents in a fixed format of Generic Exposure Information Sheets;
 - The **GES process** identifying a generic set of safe use information for classified lubricants based on typical properties and compositions of lubricants intended for a certain use.

Objective of the detailed discussion of above mentioned methodologies is to:

- Obtain detailed information on how to use these methodologies to define safe use conditions of mixtures and the final outcome with regard to safe use conditions;



- Identify the minimum input that is needed to apply these methodologies and what to do if some inputs are missing;
- Identify all kind practical issues one can run into when applying these methodologies on 'real life' examples and how to deal with them;
- Have an idea about the level of expertise that is needed to apply these methodologies;
- Have an idea about the time and effort that's needed to apply these methodologies.

Finally, this will allow for the discussed methodologies to draw some conclusions with regard to:

- Absolute minimum input that is required to apply them;
- Possible (interim) solutions for all kind of practical issues (is linked to the previous point);
- Feasibility in terms of expertise and effort;
- Possible differences in the outcome on safe use and if so, what the reason could be.

Furthermore the outcome of these discussions can also support to refine or further elaborate other methodologies that aren't discussed in detail, but e.g. uses identical or similar processes.

More detailed description of the Task Force:

New TF with representatives of Cefic and DUCC set up to prepare for ENES5 and to address several actions identified during the breakout sessions at ENES4 related to exposure scenario information for mixtures.

Results of the TF after ENES4

As mentioned above the TF was set up after ENES4. Results of the work done by the TF will be presented at ENES5.



4.2 ENVIRONMENTAL ASPECTS of EXPOSURE SCENARIOS

TITLE: - Dealing with the environmental aspects of the exposure scenario information in the Safety Data Sheets of adhesive / sealant mixtures

Objectives: FEICA presents an approach for finding out how much detail from the environmental part of the substance Exposure Scenario needs to be provided in the SDS of an adhesive / sealant mixture. At the top of the supply chain, manufacturers / importers annex appropriate Exposure Scenarios to the (SDS) of raw substances. The SDS annexes outline the operational conditions and risk management measures. These have been determined in substance risk assessment to establish the conditions of safe use and are jointly referred to as exposure determinants.

The users of adhesives and sealants typically receive SDS for mixtures. In many cases, the end users of adhesives and sealants may be overwhelmed by the detailed risk assessment information. This is particularly true for environmental safety, the assessment of which produces a complex set of information to demonstrate that there is negligible risk to the environment. This is because the releases of non-solvent constituents of adhesives and sealants to the environment may be low or because the releases of solvents to air may not result in environmental risks. In case large quantities of solvents are released from a process, the VOC is in place and demands that emission controls are put into place, regardless of environmental risks.

Expectations: From the perspective of end users of adhesives and sealants it may thus be preferable to obtain (through the safety data sheets) relatively straightforward instructions on operational conditions and risk management measures (if necessary). The FEICA presentation outlines the conditions under which it is sensible for the producers of adhesives and sealants to provide a reduced set of information to their customers such that the SDS are understandable. It also outlines how to justify the simplification. The starting point for the justification is that adhesives and sealants are destined to remain on a substrate and that releases to the environment are in contrast with the purpose of the adhesive application.